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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,006	09/17/2001	Robert J. Schneider	5914-084-999	7849

20583 7590 07/15/2005

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,006	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,24-29,31-34 and 36-38* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,24-29,31-33 and 36-38* is/are rejected.

7)☒ Claim(s) *37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/07/2005 has been entered. The office action on RCE follows:

Response to Amendment

This is a response to the amendment filed 06/07/05. Claims22, 29, 32, 33, 34 have been amended. New claims 36-38 are added. The status of claims in the application is summarized:

Claims 1-21, 23, 30, 35 have been canceled.

Claims 22, 24-29, 31-34, 36-38 are pending.

Claims 22, 24-29 31-33, and 36-38 are considered.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22 and 24-39, , 31-34, 36-38 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action on the same ground as stated in the previous office action.

3. In response to the previous Office Action, Applicants argue that the in vitro experiment is the first step of the in vivo experiment, and the toxicity of the drug and therapeutic dosage should

be determined by a person skill in the art. Therefore, it should not be used as basis of the rejections.

4. Applicants' argument has been respectfully considered; however, it is still not found persuasive because the specification does not provide any in vitro evidence for most of the species of calcium inhibitors listed in claims 28, 32, 33 and 38 except cyclosporine to support that every one of them can inhibit HBV infection in vitro even though the non-toxic therapeutic dosage can be determined by the person skill in the art.

5. Because the specification does not prove sufficient evidence to support the broadly claimed invention, considering the high unpredictability of using many claimed toxic calcium inhibitor for treating patients, the rejection is maintained.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22, 24-29 31-33, and 36 are still rejected under 35 U.S.C. 102(b) as being anticipated by Frederich et al. (Z. Gastroenterol 1988, Vol. 26, pp. 265-270) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and argue that Frederich et al.do not teach every limitation or element in the claims, and or he does not mention about the inhibition of HBV replication via modulating cytosolic calcium mechanism by the cyclosporine. Therefore, inherence rejection cannot be established. .

4. Applicants' argument has been respectfully considered; however, it is still found unpersuasive because the limitation of detecting the calcium concentration is not the active steps cited the claimed methods. The method taught by Frederich et al. uses same agent for treating same population of the patients infected with HBV, while the mechanism of the treatment is not

described, the mechanism underling the clinical beneficial is not an active step of the method in the claims and it does not add any manipulation steps of the claimed method. Regarding to the mechanism of modulating calcium concentration in the cytoplasm, the mechanism of cyclosporine is able to inhibit the calcium influx has been known in the art in light of the disclosures by may references such as Crodoso et al. (Biochem J. 1997, Vol. 327, pp. 795-801 see Figs. 6 and 1st column of text on page 799, Fig. 7 and 1st column text on page 800), Sari NE (Biol. Chem. 1997, Vol. 378,No. 10, pp. 1163-1166, see abstract only), Evtodienko et al. (Biochem. Mol. Biol. Int. 1995, Vol. 35, No. 5, pp. 1113-1121, see abstract) and Crompton et al. (Biochem. J. 1994, Vol. 302, (pt 1, pp. 181-185, see abstract). Therefore, no matter the reference discloses or not, it always exists. Hence the rejection is maintained.

New ground of rejection:

New Matter Objection

The amendment filed on June 07, 2005 is objected under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials which are not supported by the original disclosure are claim 37 because the method for measuring those marker by treatment of calcium modulator is not disclosed in the specification as it was originally filed.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The case law Vas-Cath. V. Makurkar, 19USPQ2d 111, clearly states "applicant must convey with reasonable clarity to those skilled in the art, as of the filling date sough, he or she was in possession of the invention. The invention is, for purpose of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification should "clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Moreover, to be in the possession of any claimed invention, the applicants must show that a significance of conception and reduction to practice was reached before the application was filed. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C § 112 is severable from its enablement provision (See page 1115), i.e. even if the clamed method is enabled, it does not meant that applicants has the possession since applicants did not describe or show conception and reduction of practice at the application was originally filed.

In the instant case, while each method can be tested according to the state of art, it only indicates the claimed method may be enabled. In particularity, the application does not describe about how the claimed method has been manipulated. Moreover, applicants have not shown a conception and reduction of practicing the claimed invention at the application was originally filed.

Therefore, the claimed invention in the current application is a new matter and applicants do not have the possession of claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

Bao Qun Li

07/12/205